In the United States Court of Federal Claims

No. 19-238V
Filed: May 14, 2025[†]

AMY FAULKENBERRY, on behalf of her minor son, WCF,

***Petitioner*,**

v.

THE SECRETARY OF HEALTH AND HUMAN SERVICES,

***Respondent*.**

Milton Clay Ragsdale, IV, Ragsdale LLC, Birmingham, AL, for Petitioner.

Madelyn E. Weeks, Trial Attorney, *Alexis B. Babcock*, Assistant Director, *Heather L. Pearlman*, Deputy Director, *C. Salvatore D'Alessio*, Director, *Brian M. Boynton*, Principal Deputy Assistant Attorney General, Torts Branch, Civil Division, U.S. Department of Justice, Washington, D.C., for Respondent.

MEMORANDUM OPINION AND ORDER

TAPP, Judge.

Petitioner, Amy Faulkenberry ("Ms. Faulkenberry"), on behalf of her minor son ("WCF"), petitioned for compensation, alleging that WCF suffered from anti-NMDAR encephalitis after receiving the hepatitis A vaccine and/or influenza ("flu") vaccine.[1] (Pet., ECF

[†] This Order was originally filed under seal on April 24, 2025. (ECF No. 101). The Court provided parties the opportunity to review this opinion for any proprietary, confidential, or other protected information and submit proposed redactions no later than May 8, 2025. The parties filed a Joint Status Report indicating that they did not seek any redactions. (ECF No. 104). Thus, the sealed and public versions of this Order are identical, except for the publication date and this footnote.

[1] The Special Master included a brief description of anti-NMDAR encephalitis. *See Faulkenberry on behalf of WCF v. Sec'y of Health & Hum. Servs.*, No. 19-238V, 2024 WL 4892507, at *2 (Fed. Cl. Spec. Mstr. Nov. 1, 2024); (Decision, ECF No. 95). For approximately 70% of patients, initial symptoms include headache, fever, nausea, vomiting, diarrhea, and some psychiatric symptoms. *See id.* (citing Josep Dalmau et al., Clinical experience and laboratory investigations in patients with anti-NMDAR encephalitis, 10 LANCET NEUROL. 63 (2011); filed as Spec. Mstr. Ex. A-2.). For children, initial symptoms include seizures and status epilepticus,

No. 1). The Special Master concluded that Ms. Faulkenberry "failed to show how either a hepatitis A vaccine or a flu vaccine can cause anti-NMDAR encephalitis." *Faulkenberry on behalf of WCF v. Sec'y of Health & Hum. Servs.*, No. 19-238V, 2024 WL 4892507, at *1 (Fed. Cl. Spec. Mstr. Nov. 1, 2024); (Decision, ECF No. 95). The Special Master denied compensation because Ms. Faulkenberry failed to present a medical theory supporting causation between the vaccine and anti-NMDAR encephalitis. *See id* at *6.

Ms. Faulkenberry seeks review, (ECF No. 97), arguing the Special Master used incorrect legal standards when analyzing evidence of general causation and assessing her medical theory. (Mem. Mot. for Rev. ("Pet'r's Mem."), ECF No. 97-1). The Court **DENIES** Ms. Faulkenberry's Motion for Review and **AFFIRMS** the Special Master's decision.

I. Background

WCF's diagnosis was preceded by multiple episodes of respiratory syncytial virus ("RSV"), bronchiolitis, and an upper respiratory infection ("URI"). *Faulkenberry*, 2024 WL 4892507 at *1 (citing Pet'r's Ex. 4 at 3–6, ECF No. 9). At his eighteen-month checkup, WCF's physician administered the hepatitis A and flu vaccines. *Id.* WCF's respiratory difficulties continued with new symptoms manifesting. *See id.* Following receipt of the vaccines, doctors again treated WCF for URI, vomiting, and on a separate occasion, convulsions. *Id.* at *1–2. In the following weeks, multiple pediatricians and neurologists examined WCF, and he tested positive for NMDA antibodies. *Id.* at *2.

Ms. Faulkenberry petitioned for vaccine compensation on February 12, 2019. (*See generally* Pet.). Using a preponderance of the evidence standard, the Special Master found Ms. Faulkenberry had failed to present persuasive evidence that the hepatitis A vaccine and/or flu vaccine *could* cause anti-NMDAR encephalitis. *See generally Faulkenberry*, 2024 WL 4892507. The Special Master's findings chiefly relied on a review of scientific literature and testimony from admitted experts Dr. Lydia Marcus ("Dr. Marcus"),[2] retained by Ms. Faulkenberry, and Dr. Eric Lancaster ("Dr. Lancaster"),[3] retained by the Secretary of Health and Human Services ("the Secretary"). *See id.* at *3 (citing Ex. 23, ECF No. 40; Ex. B, ECF No. 46).

Both parties' experts agree that WCF's diagnosis is anti-NMDAR encephalitis; however, they differ on whether WCF's diagnosis should be attributed to the vaccine. *See generally Faulkenberry*, 2024 WL 4892507 at *3–5. The experts primarily disagreed on three aspects of

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which is followed by "decreased responsiveness, alternating between agitation and catatonia, and marked by abnormal movements and autonomic instability." *Id.* The Special Master noted that approximately 75% of patients recover or experience mild complications; however, some will be hospitalized for several months and need physical and behavioral rehabilitation. *See id.*

[2] Dr. Marcus is a board-certified pediatric neurologist and author of a pending article on anti-NMDAR encephalitis. *See Faulkenberry*, 2024 WL 4892507, at *3 (citing Ex. 22, ECF No. 40).

[3] Dr. Lancaster is a board-certified neurologist with "expertise in antibody-mediated neurologic disorders" and has treated adult patients with anti-NMDAR encephalitis. *See Faulkenberry on behalf of WCF*, 2024 WL 4892507, at *3 (citing Ex. A, B, ECF No. 46).

this case: (1) whether there is a theory by which vaccines can cause anti-NMDAR encephalitis; (2) when WCF first manifested symptoms of his anti-NMDAR encephalitis; and (3) whether an infection, and not the vaccines, could have caused the anti-NMDAR encephalitis. *Id.*

In support of Ms. Faulkenberry's argument, Dr. Marcus recited several medical theories explaining how anti-NMDAR encephalitis can be induced; however, she appeared to focus on molecular mimicry[4] as a "plausible mechanism[.]" *Faulkenberry*, 2024 WL 4892507 at *3 (citing Pet'r's Ex. 22 at 3). Dr. Lancaster disputed this theory, arguing that the "key phenomenon which absolutely must occur for anti-NMDAR encephalitis to develop is the creation of specific antibodies that target a specific 3-dimensional epitope on the GluN1 receptor subunit[.]" *Id.* Additionally, Dr. Lancaster concluded it was highly improbable "that a denatured vaccine protein" would strongly resemble this structure.[5] *Id.* (citing Resp't Ex. A at 4, ECF No. 46). Dr. Lancaster also noted that Dr. Marcus failed to specify which vaccine would carry the NMDAR mimic or which protein was the mimic. *See id.* (citing Resp't Ex. A at 5). To this, Dr. Marcus countered that only a "plausible biologic theory" was required rather than an exact mechanism or evidence of a causal link. *Id.* (citing Pet'r's Ex. 54 at 3).

Dr. Lancaster also discussed WCF's medical history to show viable alternative causes for his anti-NMDAR encephalitis. *See Faulkenberry*, 2024 WL 4892507 at *4. (citing Resp't Ex. A at 5). WCF had a history of periodic upper respiratory infections and otitis media throughout early childhood; he would later present symptoms associated with acute gastrointestinal infection and was later diagnosed with maxillary sinusitis "when he presented with the first definite symptoms of anti-NMDAR encephalitis." *See id.* Dr. Lancaster noted that these were active infections preceding the onset of encephalitis, and any one of these causes could have led to WCF's anti-NMDAR. *See id.* Thus, Dr. Lancaster determined it to be more likely that infection was the cause of WCF's anti-NMDAR encephalitis as opposed to the receipt of vaccinations. *Id.* Dr. Marcus disagreed with Dr. Lancaster's opinion. *Id.* (arguing that even if the infection theory was accepted, the vaccinations received must be considered a "necessary and substantial cause.").

Under the National Childhood Vaccine Injury Act of 1986 ("the Vaccine Act"), petitioners must either establish: (1) an injury listed on the Vaccine Injury Table occurred within the requisite period, or (2) an unlisted injury was caused-in-fact by a vaccine listed on the Table. *See* 42 C.F.R. § 100.3; 42 U.S.C. § 300aa-11(c)(1)(C). Here, Ms. Faulkenberry petitioned for an

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[4] The molecular mimicry theory begins when a person's immune system attempts to neutralize a foreign antigen (a vaccine). *Tullio v. Sec'y of Health & Hum. Servs.*, No. 15-51V, 2019 WL 7580149, at *12–14 (Fed. Cl. Spec. Mstr. Dec. 19, 2019). In autoimmune diseases, the immune response goes awry attacking not only the foreign antigen but also the body's own tissues. *Id.* at 12. Molecular mimicry posits this malfunction occurs when the "structure of the foreign invader resembles (or mimics) the structure of cells in the body[,]" confusing the immune system, which in turn attacks the host. *Id.* ("[A] process sometimes known as "breaking tolerance.").

[5] Denatured means to modify the molecular structure of something such as a protein or DNA. *Denatured*, Merriam-Webster's Dictionary, https://www.merriam-webster.com/dictionary/denatured (last visited Apr. 19, 2025).

unlisted injury; thus, she was required to establish causation. To demonstrate actual causation, Ms. Faulkenberry was required to show by preponderant evidence: "(1) a medical theory connecting the vaccination and injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury." *Althen v. Sec'y of Health & Hum. Servs.*, 418 F. 3d 1274, 1278 (Fed. Cir. 2005) (the *Althen* test).

The Special Master explained that to prevail, Ms. Faulkenberry must establish her case by a preponderance of the evidence for each *Althen* prong. *Faulkenberry*, 2024 WL 4892507, at *6 (citing *Althen*, 418 F.3d at 1278). He also emphasized the importance of distinguishing between "preponderant evidence" and "medical certainty," stating that while preponderant evidence is required, proof of medical certainty is not. *Id.* In accordance with this standard, the Special Master rejected Ms. Faulkenberry's broad argument that she must merely establish a *plausible* medical theory of causal connection. *See id.* at *7. Despite finding that Ms. Faulkenberry improperly argued that a plausible theory was sufficient, the Special Master went on to evaluate the evidence she provided to see if it met the preponderance standard. *See id.* 8–14.

The Special Master found that the epidemiologic evidence relied upon by Ms. Faulkenberry was not persuasive. *See Faulkenberry*, 2024 WL 4892507, at *8 (noting that Plaintiff's expert relied on an abstract[6] more than three years old and not cited by any special master). He also required full versions of medical articles rather than abstracts. *Id.* (holding abstracts lack the benefit of peer reviews or scrutiny from the scientific community). Further still, the Special Master identified the limited information in the abstract Dr. Marcus used as a "methodological flaw." *Id.* (finding the abstract relied on the Vaccine Adverse Event Reporting System ("VAERS") database, which is not a reliable source) (citing *Hazlehurst v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 473, 488 (2009), *aff'd*, 604 F.3d 1343 (Fed. Cir. 2010); *Hennessey v. Sec'y of Health & Hum. Servs.*, No. 01-190V, 2009 WL 1709053, at *33 (Fed. Cl. Spec. Mstr. May 29, 2009)).

Moreover, the Special Master also found the four case reports Dr. Marcus submitted to be unsubstantiated. *Faulkenberry*, 2024 WL 4892507, at *8. "In general, case reports provide little, if any, information helpful to determining causation because they present only a temporal sequence of events in which the vaccination preceded an adverse health event." *Id.* at *9 (citing *K.O. v. Sec'y of Health & Hum. Servs.*, No. 13-472V, 2016 WL 7634491, at *11–12 (Fed. Cl. Spec. Mstr. July 7, 2016)). Apart from this, he determined that the case reports also lacked merit. *See id.* Among those case reports, one was an abstract,[7] two discussed vaccines other than the

[6] Nour Jedidi, et al., *Encephalitis after Influenza Vaccination in the United States: A CDC/FDA Vaccine Adverse Event Reporting System Study, 1990–2018* (3052). 19 NEUROLOGY, supplement 15 (2021); (Ex. 50, ECF No. 70).

[7] Teodora Cartisano and Jennifer Kicker, *Anti-N-methyl-D-Aspartate Receptor Encephalitis in 7-Month Old Infant Following Influenza Vaccination (P5.136)*, 86 NEUROLOGY, supplement 16 (2016); (Ex. 51, ECF No. 70).

hepatitis A and flu vaccines,[8] and the fourth discussed a disease other than anti-NMDAR encephalitis.[9] *See id.* Thus, the Special Master concluded that the expert's extrapolations from these case reports were unpersuasive. *See id.*

As for disclosing medical theories, the Special Master noted the lack of explanation linking either vaccine received by WCF to anti-NMDAR encephalitis. *See Faulkenberry*, 2024 WL 4892507, at *9. The Special Master criticized Dr. Marcus and Ms. Faulkenberry for listing multiple mechanisms and/or theories but failing to meaningfully engage with the theories. *Id.* at *10. Since both Ms. Faulkenberry and Dr. Marcus primarily focused on molecular mimicry, the Special Master centered his analysis on case law analyzing this medical theory. *See id.* at *10–11. The Special Master found that Dr. Marcus did not "persuasively establish the reliability of the molecular mimicry theory in the context of anti-NMDAR encephalitis." *Id.* at *12. The Special Master determined that Dr. Marcus's opinion included many generalities, lacked explanations for the methodology or results of cited studies, and mentioned no hypothesis of how the vaccines could lead to the "creation of antibodies to the specific protein that causes anti-NMDAR encephalitis." *Id.* at *12–14. Accordingly, the Special Master determined that Ms. Faulkenberry failed to meet prong one of the *Althen* test. *See id.* at *15.

II. Analysis

Ms. Faulkenberry asks the Court find that the Special Master applied the incorrect standard to analyze whether the vaccine caused WCF's injuries. (*See generally* Pet'r's Mem.). When reviewing a special master's decision, the Court must determine if the decision is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law[.]" 42 U.S.C. § 300aa-12(e)(2)(B). Accordingly, the Court applies this arbitrary and capricious standard to factual findings and *de novo* to legal conclusions. *See Munn v. Sec'y of Health & Hum. Servs.*, 970 F.2d 863, 870 (Fed. Cir. 1992).

With a mixed question of law and fact, "the standard of review . . . depends on whether answering it entails primarily legal or factual work." *Echols v. Sec'y of Health & Hum. Servs.*, 165 Fed. Cl. 9, 16 (2023) (citations omitted). In vaccine cases, the Court does not "reweigh" factual evidence, question whether the special master correctly evaluated the evidence, or re-examine the probative value of the evidence. *Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1249 (Fed. Cir. 2011); *see also Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1360 (Fed. Cir. 2000). Neither does the Court "examine the probative value of the evidence or the credibility of the witnesses." *Porter*, 663 F.3d at 1249.

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[8] Dominique Endres, *Psychiatric Presentation of Anti-NMDA Receptor Encephalitis*, 10 FRONT. NEUROL. 1086 (2019); filed as Exhibit 52. Caroline Hofmann et al., *Anti-NMDA receptor encephalitis after TdaP-IPV booster vaccination: cause or coincidence?*, 258 J. NEUROL. 500 (2010); (Ex. 30, ECF No. 40).

[9] Isabella Van Ussel et al., *Encephalitis related to a H1N1 vaccination: case report and review of the literature*, 124 CLIN. NEUROL. NEUROSURG. 8 (2014); (Ex. 36, ECF No. 41).

Rather, the Court upholds the special master's decision if they "considered the relevant evidence of record, dr[ew] plausible inferences and articulated a rational basis for the decision[.]" *Hines on behalf of Sevier v. Sec'y of Health & Hum. Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991) (holding that "reversible error [is] extremely difficult to demonstrate"). The standard of review is "highly deferential." *Cucuras v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 537, 541 (1992), *aff'd*, 993 F.2d 1525 (Fed. Cir. 1993). The Court cannot "substitute its judgment for that of the special master merely because it might have reached a different conclusion." *Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 718 (2009). So long as the special master's factual determination is "based on evidence in the record that is not wholly implausible, we are compelled to uphold that finding as not being arbitrary or capricious." *Cedillo v. Sec'y of Health & Hum. Servs*., 617 F.3d 1328, 1338 (Fed. Cir. 2010).

As previously stated, special masters and this Court apply the *Althen* test to show actual causation. *Althen*, 418 F.3d at 1278. Under this test, petitioners must show by preponderant evidence a medical theory causally connecting the vaccination and the injury, a logical sequence of cause and effect showing that the vaccination was the reason for the injury, and a showing of a proximate temporal relationship between vaccination and injury. *Id.* The parties do not dispute that it is the petitioner's burden to establish its case by a preponderance. (Pet'r's Mem. at 15; Def.'s Resp. at 6, ECF No. 100). The preponderance standard of proof is a statutory requirement and applies to each individual prong of the *Althen* test. *See Olson v. Sec'y of Health & Hum. Servs.*, 758 F. App'x 919, 922 (Fed. Cir. 2018) (citing *Oliver v. Sec'y of Health & Hum. Servs.*, 900 F.3d 1357, 1361 (Fed. Cir. 2018)); 42 U.S.C. § 300aa-13(a)(1)(A). A petitioner must satisfy all three prongs to demonstrate causation. *See Althen*, 418 F.3d at 1274.

Althen prong one requires the petitioner to show "a medical theory causally connecting the vaccination and the injury." *Althen*, 418 F.3d at 1278. The Federal Circuit has interpreted prong one of the *Althen* test and the Vaccine Act to find that causation must be proven by a preponderance of the evidence. *See* 42 U.S.C. § 300aa-13(a)(1)(A); *Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1355 (Fed. Cir. 2019); *LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1341 (Fed. Cir. 2014). The Federal Circuit and this Court have clarified the preponderance standard requires "the trier of fact to believe that the existence of a fact is more probable than its nonexistence[.]" *LaLonde*, 746 F.3d at 1338–39. Precisely, "simply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of proof." *Id.* at 1341 (citing *Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1332 (Fed. Cir. 2010).

The petitioner must provide a "reputable medical theory" that the vaccine can cause the alleged type of injury. *Althen*, 418 F.3d at 1278; *see also Pafford v. Sec'y of Health & Hum. Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006) (holding the vaccination must be "a substantial factor in causing the illness, disability, injury or condition and that the harm would not have occurred in the absence of the vaccination."). Ultimately, a special master must determine whether the medical theory advanced by the petitioner and their expert is "more probable than not[.]" *Althen*, 418 F.3d at 1279–80 (citing *Hellebrand v. Sec'y of Health & Hum. Servs.*, 999 F.2d 1565, 1572–73 (Fed. Cir. 1993)).

A special master must review record evidence to assess the preponderance standard but is at liberty to determine the weight of each piece of evidence. *See generally Knudsen v. Sec'y of*

Health & Hum. Servs., 35 F.3d 543, 549 (Fed. Cir. 1994); *Hodge v. Sec'y of Health & Hum. Servs.*, 164 Fed. Cl. 633, 641–42 (2023). Furthermore, when evaluating expert testimony, a special master "may conclude that there is simply too great an analytical gap between the data and the opinion proffered." *Cedillo*, 617 F.3d at 1339 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)); *LaLonde*, 746 F.3d at 1341 (affirming the special master's findings that the expert's reliance on a theory that is "unsupported by literature" insufficiently proves causation). A special master is also not obligated to accept an "expert[s] opinion testimony that is connected to the existing data or methodology 'only by the *ipse dixit* of the expert[.]'" *Jarvis v. Sec'y of Health & Human Servs.*, 99 Fed. Cl. 47, 61 (quoting *Cedillo*, 617 F.3d at 1339 (internal citations omitted).

Here, Ms. Faulkenberry raises two main objections to the Special Master's decision. (*See* Pet'r's Mem. at 3). First, Ms. Faulkenberry claims the Special Master heightened Petitioner's burden by requiring direct proof of how anti-NMDAR encephalitis is caused. (*See generally id.* at 4–14). Second, Ms. Faulkenberry argues the Special Master required her to "present a persuasive theory" which improperly elevated her burden under prong one of the *Althen* Test. (*See generally id.* at 14–20). The Court disagrees with both of Ms. Faulkenberry's arguments and finds that the Special Master did not impermissibly raise the burden of proof and used the correct standard when evaluating her medical theory.

First, Ms. Faulkenberry contends that the Special Master erred by requiring direct proof of causation, thereby raising the burden of proof. (*See* Pet'r's Mem. at 4–14). Essentially, Ms. Faulkenberry's disagreement pertains to the sufficiency of her evidence. Ms. Faulkenberry seems to take issue with the outcome of the Special Master's decision and the weighing of the evidence; however, she couches her argument as a legal dispute by discussing the standard of proof required for causation. (Pet'r's Mem. at 5 (arguing she was only required to show "by a preponderance of evidence . . . that her medical theory was biologically plausible and reliable within the context of available medical knowledge.")).[10] She contends that in the absence of direct proof, as exists here, circumstantial evidence may be sufficient to establish causation. (*Id.* at 4). While the Court agrees with this in principle, the Court agrees with the Special Master that the gaps in Ms. Faulkenberry's proof do not surpass the requirement of preponderant evidence.

Ms. Faulkenberry claims the Special Master required direct proof of causation by analyzing each piece of medical literature in isolation rather than considering them as a

[10] (*See* Pet'r's Mem. at 3–4 ("[i]nstead of weighing whether Petitioner's evidence in this case met the preponderance standard, he held Petitioner to a level of proof that may be available for some other conditions, but is scientifically unknown for anti-NMDAR encephalitis"), 5 ("[i]nstead of weighing Petitioner's evidence with this in mind, the Special Master found that a 'gap in Dr. Marcus's opinion . . . deprive[d] [it] of sufficient evidentiary weight to be reliable'"), 6 ("[i]nstead of weighing this testimony, the Special Master ignored the evidence and concluded that this 'gap' should drive the outcome of the case"), 6 ("instead of weighing the evidence in this case to determine whether it meets petitioner's burden, the Special Master compared this case to other cases evoking the same medical theory of molecular mimicry"), 8 ("the law is clear that special masters must weigh a petitioner's proof by a preponderance of the proof in that individual case"), 12 ("[t]he law required the Special Master to weigh the available evidence for how the vaccination could have caused [WCF's] anti-NMDAR encephalitis")).

collective to support her medical theory. (Pet'r's Mem. at 13). This assertion is unsupported. The Special Master reviewed and determined that Ms. Faulkenberry's epidemiological study was unreliable, her case reports were problematic, and that her expert struggled to present a theory explaining how vaccinations can cause anti-NMDAR encephalitis. *Faulkenberry*, 2024 WL 4892507, at *8–15. From this collective assessment, the Special Master determined that Ms. Faulkenberry had failed to meet her burden. *Id.* at *15. Rather than evaluate Ms. Faulkenberry's medical literature "by itself," as Ms. Faulkenberry suggests, the record demonstrates that the Special Master evaluated the entirety of her evidence.

Ms. Faulkenberry also alleges the Special Master raised the burden of proof when he "required empirical confirmation or other direct proof that the vaccine at issue *does* cause the injury alleged[.]" (Pet'r's Mem. at 13). Specifically, Ms. Faulkenberry states the Special Master improperly "demanded direct evidence" demonstrating how either the Hepatitis A or flu vaccines "led to the creation of antibodies to the specific protein that causes anti-NMDAR encephalitis." (*Id.* at 13–14). Ms. Faulkenberry argues that her expert is permitted to synthesize a medical theory by "combined references to circumstantial evidence of biologic plausibility in medical literature." (*Id.*). Dr. Marcus's theory primarily advanced a theory of molecular mimicry.[11]

The Special Master explained that the Federal Circuit and this Court consistently require a petitioner to present at least some persuasive or reliable evidence to support such a theory. *Faulkenberry*, 2024 WL 4892507, at *10 (citing *Tullio v. Sec'y of Health & Hum. Servs.*, No 15-51V, 2019 WL 7580149, at *12–14 (Fed. Cl. Spec. Mstr. Dec. 19, 2019), *mot. for review. denied*, 149 Fed. Cl. 448 (2020)). The Special Master also articulated that requiring such evidence, when evaluating the theory of molecular mimicry, does "not elevate the petitioner's burden of proof." *Id.* at *11 (citing *Morgan v. Sec'y of Health & Hum. Servs.*, 148 Fed. Cl. 454, 476–77 (2020), *aff'd in non-precedential opinion*, 850 F. App'x 755 (Fed. Cir. 2021)). *Faulkenberry*, 2024 WL 4892507, at *10. Here, the Secretary highlighted that Ms. Faulkenberry's molecular mimicry theory contained a "foundational deficit" in that it was unclear whether Dr. Marcus believed that the alleged mimic resided in the flu vaccine, Hep A vaccine, or some combination. *Id.* at 12 (citing Resp't's Br. at 24–25, ECF No 88). Further still, the Secretary argued that Dr. Marcus utilized the generalized term "autoimmune encephalitis" which made it unclear "whether the percentages she cites apply to WCF's specific condition of anti-NMDAR encephalitis or other types of encephalitis." *Id.* The Special Master agreed with the Secretary's arguments.

Dr. Marcus opined that "molecular mimicry, acting possibly in combination with other mechanisms," is a reliable theory amongst the medical community to explain vaccine-induced autoimmunity. *Faulkenberry*, 2024 WL 4892507, at *13. However, the Special Master found that this statement was overly generalized:

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[11] Dr. Marcus raised several other theories including "host infection, occult neoplasm," "polyclonal lymphocyte activation, epitope spreading, . . . and antigen complementarity." *Faulkenberry*, 2024 WL 4892507, at *14. Dr. Marcus failed to engage with the alternate theories "in a meaningful way." *Id.* at 10. Therefore, the Special Master determined reliance on these alternate theories to be non-persuasive. *Id.* at 14 (citing *Baron v. Sec'y of Health & Human Servs.*, No. 14-341V, 2019 WL 2273484, at *17 (Fed. Cl. Spec. Mstr. Mar. 18, 2019)).

> This statement conflates a very general biological fact, namely that molecular mimicry has been proven to occur in very rare cases for specific diseases with specific triggers, with the question of whether molecular mimicry actually occurs for this specific disease with this specific mimic. Dr. Marcus does not provide any reliable evidence that molecular mimicry occurs for the specific vaccine in question to cause antiNMDAR encephalitis. It is entirely insufficient for Dr. Marcus to just assert that molecular mimicry exists in general, and therefore we must consider this the likely disease mechanism in this case. If we accept Dr. Marcus's reasoning, then we would have to conclude that any vaccination can cause every autoimmune disease simply because molecular mimicry has been shown with other stimuli and other diseases.

Id. (citations omitted).

Both Dr. Lancaster and Dr. Marcus agreed that the creation of auto-antibodies was an essential event that must occur for anti-NMDAR encephalitis to develop. *Faulkenberry*, 2024 WL 4892507, at *13. However, the Special Master found that Dr. Marcus failed to "hypothesize any way that the hepatitis A vaccine and/or the flu vaccine [could] lead[] to the creation of antibodies to the specific protein that causes anti-NMDAR encephalitis." *Id.* The Special Master determined that this lack of hypothesis was fatal to the believability of Dr. Marcus's opinion. *Id.* ("This leaves a gap in Dr. Marcus's opinion regarding molecular mimicry and deprives Dr. Marcus's opinion of sufficient evidentiary weight to be reliable.").

Additionally, the Special Master found Dr. Marcus's reliance on two articles to be of little value. *Faulkenberry*, 2024 WL 4892507, at *13–14. One article explored potential links between vaccines and anti-NMDAR encephalitis using analysis across six vaccines including the H1N1 influenza vaccine. *Id.* at *14 (noting the article excluded the hepatitis A vaccine). The Special Master criticized the article for failing to discuss any connection between its findings and found its conclusion was limited. *Id.* Ultimately, the Special Master noted that Dr. Marcus "did little" to explain the study's methodology or results in support of her opinion. *Id.* (finding Dr. Marcus had not proposed that the articles use of "phylogenetic analysis" could "serve as a proxy for a showing of some homology."). Similarly, Dr. Marcus relied upon a second article to assert that "a study of almost 3,000 patients tested for anti-NMDAR antibodies found [a] higher prevalence of anti-NMDAR antibodies in patients with anti-influenza A IgG." *Id.* However, Dr. Lancaster noted that this article did not study patients with anti-NMDAR encephalitis, and Dr. Marcus failed to elaborate. *Id.* The Special Master found the article unhelpful. *Id.* ("Dr. Lancaster's criticism seems well-founded."). Other than her expert's assertions, Ms. Faulkenberry's theory lacked the support necessary to reach the asserted conclusions. Such a mere theory is insufficient to meet *Althen's* first prong.

Ms. Faulkenberry's related second argument claims the Special Master employed the incorrect evidentiary standard when evaluating the validity of her expert's medical theory regarding how the vaccines WCF received can cause anti-NMDAR encephalitis. (Pet'r's Mem. at 14). She argues the Special Master erred by "confusing petitioner's burden of proof (probability) with the element of causation petitioner must prove (a plausible medical theory)."

(*Id.*). Stated differently, Ms. Faulkenberry's objects not to the specific evidentiary standard of proof for *Althen* prong one, but rather to what she was required to prove and how she could prove it. (*Id.* at 15 ("Petitioner carries a burden to prove causation by a preponderance of evidence, but preponderance is not the metric the Federal Circuit has adopted to evaluate the validity of Petitioner's medical theory.")). Ms. Faulkenberry argues the validity of her medical theory can be satisfied "by setting forth a 'biologically plausible' theory of general causation" and the Special Master improperly elevated her burden by requiring a "persuasive theory[.]" (*Id.* at 14–15).

The Special Master properly identified that Ms. Faulkenberry was required to "do more than demonstrate a 'plausible' or 'possible' causal link between the vaccination and the injury; [she] must prove his case by a preponderance of the evidence." *Faulkenberry*, 2024 WL 4892507, at *7 (citing *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013)). After specifying that the preponderance standard applies to prong one, the Special Master also explained that determining whether the theory met that standard requires an evaluation of the evidence Ms. Faulkenberry supplied. *Id.* at *8 ("[I]t is conceivable that the evidence surpasses the correct threshold . . . . [f]or this reason and to demonstrate that all evidence relevant to *Althen* prong one has been considered, the undersigned will next evaluate Ms. Faulkenberry's proposed theories").

The Special Master articulated that the evidence supplied must be of a persuasive nature. *Faulkenberry*, 2024 WL 4892507, at *7 ("the Court of Federal Claims [has generally] held that the burden of proof for *Althen* prong one is persuasive evidence."). This requirement is consistent throughout the case law from the Federal Circuit. *See Hodges v. Sec'y of Health & Hum. Servs.*, 9 F.3d 958, 967 ("[T]he factfinder must decide the reliability, consistency, and probative value of the scientific evidence, with the guidance of scientific opinion."); *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1384 (Fed. Cir. 2021) (affirming the special master's standard in requiring a "reputable medical theory . . . based on a sound and reliable medical or scientific explanation."); *Kottenstette v. Secretary of Health and Human Services*, 861 F. App'x 433, 440–41 (Fed. Cir. 2021) (holding proof of causation "does not 'require identification and proof of specific biological mechanisms[,]" but must be supported by a sound and reliable medical or scientific explanation) (internal citations omitted); *Knudsen*, 35 F.3d at 548–49; *See Nunez v. Sec'y of Health & Hum. Servs.*, 825 F. App'x 816, 819 (Fed. Cir. 2020) (determining whether the evidence "so persuasively" establishes the reliability of a medical theory); *Orloski v. Sec'y of Health & Hum. Servs.*, 839 Fed. App'x 538, 541 (Fed. Cir. 2021). Failure to present reliable evidence will necessarily fail to meet muster.

The Court has already determined that the Special Master devoted substantial analysis to the evidence provided by Ms. Faulkenberry in support of her case. *See generally Faulkenberry*, 2024 WL 4892507, at *8–15. However, for the variety of reasons previously highlighted, the Special Master found her evidence to be deficient which is within his purview as the fact finder. *Althen*, 418 F.3d at 1278 ("[a] persuasive medical theory is demonstrated by 'proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[,]' the logical sequence being supported by 'reputable medical or scientific explanation[.]'"); *Knudsen*, 35 F.3d at 548; *Nunez*, 825 F. App'x at 819. These deficiencies highlight the unreliability of Ms. Faulkenberry's evidence and undermines her medical theory.

Because the Special Master acted within his discretion, Ms. Faulkenberry's arguments fail. *Porter*, 663 F.3d at 1249 ("as long as a special master's finding of fact is 'based on evidence in the record that [is] not wholly implausible, we are compelled to uphold that finding as not being arbitrary or capricious.'") (internal citations omitted). The Court finds the Special Master's analysis is well-reasoned and thorough. Accordingly, the Special Master did not arbitrarily evaluate the evidence or impermissibly raise Ms. Faulkenberry's burden of proof for establishing causation.

III. Conclusion

For the stated reasons, the Court hereby **DENIES** Ms. Faulkenberry's Motion for Review, (ECF No. 97), and **AFFIRMS** the Special Master's November 1, 2024, decision. The Clerk is directed to enter judgment accordingly.

The Court has filed this ruling under seal. The parties shall confer to determine proposed redactions to which all parties agree. Per Vaccine Rule 18(b), no later than May 8, 2025, the parties shall file a joint status report indicating their agreement with the proposed redactions, attaching a copy of those pages of the Court's ruling containing proposed redactions, with all proposed redactions clearly indicated.

IT IS SO ORDERED.

s/ David A. Tapp
DAVID A. TAPP, Judge